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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,185

08/07/2006

Hans-Peter Buchstaller

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EXAMINER

LOEWE, SUN JAE Y

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

05/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,185	Applicant(s) BUCHSTALLER ET AL.	
	Examiner SUN JAE Y. LOEWE	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-13,15-24 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 12,13,15-24 and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-11,32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-25-2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 3, 5-13, 15-24 and 28-33 are pending in the instant application. Claims 14 and 25-27 were cancelled by preliminary amendment filed on September 21, 2007. Claims 2 and 4 were cancelled by amendment filed on January 25, 2008.

Response to Amendment

2. The amendments to the claims filed on January 25, 2008 were fully considered. The following grounds of rejection are withdrawn: 35 USC 112 2nd paragraph; 35 USC 102. The amendments do not overcome the 35 USC 112 1st paragraph (written description and enablement) rejections.

Response to Arguments

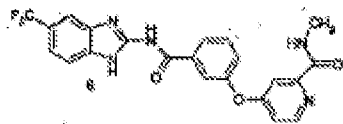
3. Applicant's remarks filed on January 25, 2008 have been fully considered. However, they are not persuasive in overcoming the 35 USC 112 1st paragraph rejections (written description and enablement). Therefore, these grounds of rejection are maintained and hereby made FINAL. See response to arguments below, Sections 5 and 6.

Claim Objections

4. Claims 1, 3, 5-11, 32 and 33 objected to for containing non-elected subject matter. Currently, examination is restricted to the elected species of

4-{3-(3-Trifluoromethyl-1H-benzimidazol-2-yl) carbamoyl} phenoxy] pyridine-2-carboxylic acid, methyl amide.

Art Unit: 1626



; thus, the elected species is the “elected subject matter.” Non-

elected subject matter: compounds of formula I that are not the species denoted above.

Applicant is respectfully directed to the restriction requirement dated July 25, 2007, excerpts below:

“ Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependant form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. ”

Claim Rejections - 35 USC § 112

(Written Description)

5. Below are responses to Applicant’s remarks:

- a) “The specification provides the skilled artisan with ample chemical structure information to immediately envision chemical species commensurate with the scope of the claimed genus of the rejected claims. ”

Applicant’s remarks do not provide for the disclosure of additional species in support of the claimed genus. It is maintained that the species disclosed are limited to those denoted in the previous office action (pg. 6-7, section entitled “Scope of Disclosure”).

- b) “ Furthermore, the Examiner asserts that disclosure of species supporting the claimed genera is limited to compounds actually reduced to practice. However, written description may be satisfied by the description of a representative number of species. Actual reduction to practice of species is not required. ”

Applicant's comment is noted. Actual reduction to practice is one of several ways that Applicant may disclose species in support of a claimed genus. Applicant is invited to point out where in the instant specification there is disclosure of species additional to those reduced to practice. Presently, in view of the reasons presented in the previous office action (pg. 6-7, “Scope of Disclosure”), it is

maintained that the scope of the disclosure is limited to the species reduced to practice.

It is maintained that 35 USC 112 1st paragraph (written description) rejection was proper.

Thus, this ground of rejection is maintained and hereby made FINAL.

(Enablement)

6. Below are responses to Applicant's remarks:

- a) "Applicants would like to submit that the Examiner is required to state what claim embodiments are enabled in the specification. The Examiner has stated that the specification is enabling for the use of compounds that have adequate written description. Applicants, respectfully request that the Examiner clarify what he maintains are enabled claim embodiments. "

The enabled claim embodiments are compounds of Formula I encompassed by the genus defined by:

R ⁶ /R ⁷ :	hydrogen or unsubstituted alkyl, haloalkyl, halogen
R ⁸ /R ⁹ :	hydrogen, unsubstituted alkyl, haloalkyl, halogen
R ¹⁰ :	hydrogen, unsubstituted alkyl, haloalkyl, halogen,
	(CH ₂) ₂ CONH-R ¹¹ wherein R ¹¹ /R ¹² =hydrogen, unsubstituted
	alkyl, haloalkyl, halogen
X/Y:	exo
Ar ¹ :	pyridinyl

(see office action, pg. 7, pg. 8). Furthermore, it is suggested for Applicant to delete the intended use language in claims 7 and 8 to overcome this ground of rejection.

- b) "Applicants respectfully request reconsideration and withdrawal of the enablement rejection because determining the activity of the species falling within the claimed genus for Raf Kinase inhibition would not require undue experimentation as numerous routine methodologies are available to the skilled artisan to assess such activity "

The suggestion to experiment (ie. test instantly claimed compounds to see if they inhibit Raf kinase) is deemed not to fulfill the requirements set forth by 35 USC 112 1st paragraph. Applicant is respectfully referred to MPEP 2164.03, excerpts below:

“The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. ”

Conclusion

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./
4-30-2008